

Translation

PATENT COOPERATION TREATY

PCT/CH2002/000707



PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 1984/PCT	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/CH2002/000707	International filing date (day/month/year) 17 December 2002 (17.12.2002)	Priority date (day/month/year)
International Patent Classification (IPC) or national classification and IPC A61F 2/44		
Applicant MATHYS MEDIZINALTECHNIK AG		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 8 sheets, including this cover sheet.

☒ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 2 sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand 28 June 2004 (28.06.2004)	Date of completion of this report 06 April 2005 (06.04.2005)
Name and mailing address of the IPEA/EP	Authorized officer
Facsimile No.	Telephone No.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/CH2002/000707

I. Basis of the report

1. With regard to the elements of the international application:*

- ☐ the international application as originally filed
- ☒ the description:
 pages _____ 1-9 _____, as originally filed
 pages _____, filed with the demand
 pages _____, filed with the letter of _____
- ☒ the claims:
 pages _____ 3-20 _____, as originally filed
 pages _____, as amended (together with any statement under Article 19
 pages _____, filed with the demand
 pages _____ 2 / 1 _____, filed with the letter of _____ 23.7.2004 2005
- ☒ the drawings:
 pages _____ 1/4-4/4 _____, as originally filed
 pages _____, filed with the demand
 pages _____, filed with the letter of _____
- ☐ the sequence listing part of the description:
 pages _____, as originally filed
 pages _____, filed with the demand
 pages _____, filed with the letter of _____

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

- These elements were available or furnished to this Authority in the following language _____ which is:
- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/fig _____

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rule 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

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III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application.

☒ claims Nos. 19, 20

because:

☐ the said international application, or the said claims Nos. _____
relate to the following subject matter which does not require an international preliminary examination (*specify*):

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. _____
are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. _____ are so inadequately supported
by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claims Nos. 19, 20

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

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Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: BOX III

Non-establishment of opinion with regard to novelty,
inventive step and industrial applicability

1. Pursuant to PCT Rule 39.1(iv), the subject matter of claims 19 and 20 was not searched. For this reason, no examination report was established for these claims (PCT Rule 66.1(e)).

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V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	5-18	YES
	Claims	1-4	NO
Inventive step (IS)	Claims	7-12, 17	YES
	Claims	1-6, 13-16, 18	NO
Industrial applicability (IA)	Claims	1-18	YES
	Claims		NO

2. Citations and explanations

2. This report makes reference to the following documents:

D1: US 4 759 766 (Büttner-Janz Karin), 26 July 1988

D2: WO 01/56513 (Michelson Gary K.), 9 August 2001

D3: US 5 556 431 (Büttner-Janz Karin), 17 September 1996

2.1 Document D1 was cited in the description, and is preferred to document DE-A-35 29 761, which is parallel to D1, because of the additional figure, 10A.

3. The subject matter of claim 1 is not novel.

Document D1 (see column 2, line 65 - column 3, line 11; column 5, lines 46-65; and figures 10, 10A and 11) discloses

an intervertebral implant having a central axis (figures 10 and 11), a top plate (11a, c) suitable for supporting the base plate of an overlying

vertebra, and a bottom plate (11b, d) suitable for supporting the covering plate of an underlying vertebra; the two plates (11a,c and 11b,d) are movable relative to one another by means of articulations arranged between the two plates (column 5, lines 60-65), each of the articulations having a rotational axis and the two rotational axes being arranged transversely to one another (column 5, lines 50-55). The two articulations are formed by a top piece joined to the top plate, a central piece (12a, b) and a piece joined to the bottom plate. One of the end articulation pieces comprises at least one concave sliding surface which is rotationally symmetrical relative to a rotational axis and the central articulation piece comprises at least one convex sliding surface which is complementary to these concave sliding surfaces. The other end articulation piece comprises at least one convex sliding surface which is rotationally symmetrical relative to the other rotational axis and the central articulation piece comprises at least one concave sliding surface which is complementary to that convex sliding surface (see, in particular, the four possible embodiments described in column 2, line 65 - column 3, line 11). The sliding surfaces are designed as partial surfaces of circular cylindrical outer surfaces (column 5, lines 50-56; see also the corresponding description in the present application, page 1, lines 27-28).

The subject matter of claim 1 therefore does not meet the requirements of PCT Article 33(2) because it lacks novelty.

4. Claims 2 and 3 relate to the arrangement of the

concave and convex sliding articulation surfaces in the intervertebral implant and are already known from document D1 (column 2, line 65 - column 3, line 11; see also point 3.1).

Moreover, the sliding surfaces known from D1 constitute partial surfaces of cylindrical outer surfaces (column 5, lines 52-53) and therefore anticipate the subject matter of claim 4.

The subject matter of claims 2-4 therefore does not meet the requirements of PCT Article 33(2) because it lacks novelty.

5. Claims 5 and 6 relate to the spatial position of the rotational axes of the individual articulations and are worded in such a way that the subjects of the two claims are mutually exclusive, since the rotational axes are either skewed relative to one another (claim 5) or lie in a single plane (claim 6).

The subject matter of claims 5 and 6 is trivial because a person skilled in the art must inevitably choose one of the two embodiments when designing articulations whose rotational axes extend transversely to one another (see also claim 1, paragraph D), and does not need any inventiveness to do so.

Claims 5 and 6 therefore fail to involve an inventive step (PCT Article 33(3)).

6. The subject matter of claim 13 differs from document D1, which represents the prior art closest to this

claim, in that the top and bottom plates each comprise at least two continuous bores with longitudinal axes which extend from the ventral side surfaces to the apposition surfaces, said bores receiving bone fixation means.

The problem solved by this design of the intervertebral body can be considered to be that of avoiding an unwanted change in the implant position relative to the adjacent vertebrae.

Both document D2 (see page 36, lines 17-32, in particular figures 43 and 45) and document D3 (see column 2, lines 51-55, in particular figures 1 and 2) disclose an intervertebral implant (D2: 800; D3: parts 1-5) which is screwed by two bone screws (D2: 900; D3: 9) to the overlying and overlying vertebrae in order to ensure a secure seat of the implant. A person skilled in the art would therefore consider the inclusion of this feature in the intervertebral implant described in D1 a conventional measure for solving the problem in question, without needing to be inventive.

Claim 13 therefore also lacks an inventive step (PCT Article 33(3)).

7. Moreover, document D3 (column 1, lines 56-66) discloses all the features of claims 14 and 15, and therefore these claims also fail to involve an inventive step.
7. Furthermore, document D2 (page 36, lines 27-28, and figures 43 and 46) discloses bores which, viewed from the ventral side surfaces, diverge from the

inner surfaces against the apposition surfaces
(claim 16) and comprise an inner thread (claim 18).

Claims 16 and 18 therefore do not involve an
inventive step (PCT Article 33(3)).

9. An intervertebral implant as per claims 1-18 is
industrially applicable (PCT Article 33(4)).